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CORPORATION, ELLIOT B. LANDER, M.D.
and MARK BERMAN, M.D.

**UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA
EASTERN DIVISION**

UNITED STATES OF AMERICA,
Plaintiff,
v.
CALIFORNIA STEM CELL
TREATMENT CENTER, INC., a
California corporation, CELL SURGICAL
NETWORK CORPORATION, a
California corporation, and ELLIOT B.
LANDER, M.D., MARK BERMAN,
M.D., individuals,
Defendants.

CASE NO. 5:18-CV-01005-JGB-KK

Hon. Jesus G. Bernal
Riverside, Courtroom 1

**DEFENDANTS'
SUPPLEMENTAL
BRIEF RE: PROPER
INTERPRETATION OF
21 C.F.R. § 1271.3(D)**

1 Defendants California Stem Cell Treatment Center, Cell Surgical Network
 2 Corporation, Elliot Lander, M.D., and Mark Berman, M.D., hereby submit this
 3 supplemental brief regarding the proper interpretation of 21 C.F.R. § 1271.3(d)
 4 (“Section 1271.3(d)”) and how that intersects with the same surgical procedure
 5 exception (“SSP Exception”) under 21 C.F.R. § 1271.15, per this Court’s directive
 6 at the conclusion of closing arguments on August 20, 2021.

7 The SSP Exception exempts from FDA oversight any “establishment that
 8 removes HCT/Ps from an individual and implants such HCT/Ps into the same
 9 individual during the same surgical procedure.” 21 C.F.R. § 1271.15. The SSP
 10 Exception therefore hinges largely on the definition of “HCT/Ps” under Section
 11 1271.3(d) and how to interpret “such HCT/Ps” relative to the first reference to
 12 “HCT/Ps” in the SSP Exception.

13 “HCT/Ps” is an acronym for “[h]uman cells, tissues, or cellular or tissue-
 14 based products,” and HCT/Ps are defined in Section 1271.3(d) as “articles
 15 containing or consisting of human cells or tissues that are intended for
 16 implantation, transplantation, infusion, or transfer into a human recipient.”
 17 21 C.F.R. § 1271.3(d).

18 Settled canons of statutory construction guide the interpretation of these
 19 provisions. In that respect, “[i]t is a cardinal principle of statutory construction that
 20 a statute ought, upon the whole, to be so construed that, if it can be prevented, no
 21 clause, sentence, or word shall be superfluous, void, or insignificant.” *TRW Inc. v.
 22 Andrews*, 534 U.S. 19, 31 (2001). As the Government acknowledged at summary
 23 judgment, a “[c]onstruction which gives effect to *all of the words* of a statute or
 24 regulation is preferred over an interpretation which renders some of the statute or
 25 regulation ineffective.” *First Charter Financial Corp. v. United States*, 669 F.2d
 26 1342, 1350 (9th Cir. 1982) (emphasis added, citation omitted); *see also United
 27 States v. Canals-Jimenez*, 943 F.2d 1284, 1287 (11th Cir. 1991) (“A basic premise
 28

1 of statutory construction is that a statute is to be interpreted so that no words shall
 2 be discarded as being meaningless, redundant, or mere surplusage.”).

3 • **A Plain Language Analysis of Section 1271.3(d)**

4 To obtain a construction of Section 1271.3 that gives effect to *all* the words
 5 in the definition, it is helpful to break that definition down into its parts. As noted,
 6 HCT/Ps are “articles containing or consisting of human cells or tissues that are
 7 intended for implantation, transplantation, infusion, or transfer into a human
 8 recipient.” 21 C.F.R. § 1271.3(d). The plain language of Section 1271.3(d) is not
 9 ambiguous. Taking each word in turn:

10 What are “articles”? “Articles” are not specifically defined by the FDCA,
 11 but common usage defines “articles” as “things . . . of a particular class” or
 12 “individual objects.” [Https://www.merriam-webster.com/dictionary/articles](https://www.merriam-webster.com/dictionary/articles);
 13 <https://www.dictionary.com/browse/article>. Thus, HCT/Ps are “things.” There is
 14 no meaningful dispute about this.

15 What type of “articles” or “things” are HCT/Ps? Per Section 1271.3(d),
 16 HCT/Ps are things “containing or consisting of” “human cells or tissues” “that are
 17 intended for implantation, transplantation, infusion, or transfer into a human
 18 recipient.” These three quoted portions each warrant individual consideration.

19 Is there a distinction between “containing” and “consisting of”? Yes,
 20 as this Court noted and the Government agreed. (8/20/21 Tr. at 15:25-16:8.)
 21 *See Bailey v. United States*, 516 U.S. 137, 146 (1995) (“We assume that
 22 Congress used two terms because it intended each term to have a particular,
 23 nonsuperfluous meaning.”). “Containing” means “to have” or “to hold” or “to
 24 include.” [Https://www.merriam-webster.com/dictionary/containing](https://www.merriam-webster.com/dictionary/containing);
 25 <https://www.dictionary.com/browse/containing>. “Consisting of” means “to be
 26 composed of or made up of.” [Https://thelawdictionary.org/consisting/](https://thelawdictionary.org/consisting/).
 27 Black’s Law Dictionary further explains that “consisting of” is “not synonymous
 28 with ‘including,’ for the latter, when used in connection with a number of specified

1 objects, always implies that there may be others which are not mentioned.”
 2 <Https://thelawdictionary.org/> consisting/. Giving effect to this plain language and
 3 the recognized distinction between the words used, when a “thing” is “containing”
 4 something or things, it also may contain or include other things. Where a “thing”
 5 is “consisting of” something or things, the thing is made up of only those things.
 6 Thus, the articles that constitute HCT/Ps under Section 1271.3(d) can include
 7 human cells or tissues among other things, or the articles can be made up of *only*
 8 human cells or tissues. Simplified down, the articles that constitute HCT/Ps *are*
 9 human cells or tissues—either in part or in whole.

10 Next, is there a distinction between “human cells” and “tissues”? Yes.
 11 That is evident by the disjunctive “or” language in Section 1271.3(d) and it is an
 12 undisputed fact in this case. Cells are the smallest and most basic functional
 13 structural units in the human body. Cells can only be removed from an individual
 14 along with larger systems, such as the tissues or organs that they comprise. (See
 15 5/7/21 PM Tr. 19:9-12 (Yong); 5/11/21 AM Tr. 112:13-19 (Berman)). Thus, even
 16 though cells cannot be removed without also removing the larger systems they
 17 comprise, the unambiguous language of Section 1271.3(d) contemplates that cells,
 18 distinct from their surrounding tissues, can be HCT/Ps.

19 Finally, are the human cells or tissues “intended for implantation”? This
 20 aspect of the definition is critical to understanding whether and what “human cells
 21 or tissues” are the HCT/Ps at issue. HCT/Ps do not encompass just *any* “article
 22 containing or consisting of human cells or tissues.” If the human cells or tissues
 23 are *not* “intended for implantation,” they are not HCT/Ps. If the human cells or
 24 tissues *are* “intended for implantation,” they are HCT/Ps.

25 Thus, HCT/Ps are not defined in any way by what or how any of the cells or
 26 tissues are removed. HCT/Ps are defined only by whether they are “human cells or
 27 tissues intended for implantation.” And this makes sense. As noted, it currently is
 28 not technologically possible to remove *only* cells and not the larger systems they

1 comprise, and it certainly was not possible to remove only cells when Section
 2 1271.3(d) was promulgated. If HCT/P status depended on what was removed,
 3 inclusion of “cells” in the definition of HCT/Ps would be superfluous because cells
 4 cannot be removed without tissue. Similarly, the fact that tissues comprised of
 5 cells are removed does not render the tissues the HCT/Ps. Rather, HCT/P status
 6 depends on what “human cells or tissues”—it could be either or both—are
 7 “intended for implantation.” If the tissues removed from an individual are
 8 “intended for implantation,” those tissues are HCT/Ps under Section 1271.3(d).
 9 And if the tissues removed from an individual are not “intended for implantation,”
 10 like the adipose tissues at issue here, those tissues are not HCT/Ps. Likewise,
 11 if the cells isolated from removed tissues are the cells “intended for implantation,”
 12 like the SVF cells at issue here, those cells are HCT/Ps under Section 1271.3(d).
 13 (See 8/20/21 Tr. at 19:20-20:5.)

14 • **How Section 1271.3(d) Intersects With The SSP Exception**

15 Having simplified the meaning of HCT/Ps under Section 1271.3(d) down to
 16 “human cells or tissues intended for implantation,” the SSP Exception applies
 17 when an “establishment removes HCT/Ps [or human cells or tissues intended for
 18 implantation] from an individual and implants such HCT/Ps [or human cells or
 19 tissues intended for implantation] into the same individual during the same surgical
 20 procedure.” 21 C.F.R. § 1271.15.

21 With the plain language definition of HCT/Ps limited to the “human cells or
 22 tissues intended for implantation,” so long as the cells intended for implantation
 23 are removed from a patient and implanted back into the same patient in the same
 24 procedure, the SSP Exception applies.

25 That is precisely what the SVF Procedure does here. It removes adipose
 26 tissues from the patient; those adipose tissues are not intended for implantation and
 27 therefore are not the relevant HCT/Ps. The SVF Procedure then isolates from the
 28 removed adipose tissue the SVF cells that *are* intended for implantation; those

1 SVF cells therefore are the relevant HCT/Ps, i.e., the “remove[d] HCT/Ps” under
 2 the SSP Exception. The SVF Procedure then implants those SVF cells, i.e., “such
 3 HCT/Ps,” back into the same patient during the same procedure. Thus, the SSP
 4 Exception applies.

5 The Government has argued the SSP Exception does not apply to the SVF
 6 Procedure because the HCT/Ps that are implanted (undisputedly, the SVF cells)
 7 are not “such HCT/Ps” that are removed. But that argument reflects a
 8 misinterpretation of HCT/Ps under Section 1271.3(d). By focusing only on what is
 9 removed, i.e., the adipose tissues, to define the HCT/Ps, the Government ignores
 10 the plain language of Section 1271.3(d) that limits HCT/Ps to those “human cells
 11 or tissues *intended for implantation.*” The SVF Procedure does not ever consider
 12 the removed adipose tissues to be “intended for implantation.” The SVF Procedure
 13 only contemplates that the SVF cells that are isolated from the removed adipose
 14 tissues are the “cells” “intended for implantation.” Therefore, only the SVF cells
 15 are the relevant HCT/Ps for purposes of the SSP Exception.

16 Lastly, according to the evidence adduced at trial, the SVF cells that are
 17 removed from a patient are the very same SVF cells or “such HCT/Ps” that are
 18 implanted in the patient in the same surgical procedure. (*See* 5/12/21 AM Tr. 85:7-
 19 86:8; 89:21-91:1, 99:24-101:13 (Reid); 5/12/21 PM Tr. 85:12-18 (Lander)).
 20 Thus, the SSP Exception applies to the SVF Procedure.

21 Dated: August 27, 2021

Respectfully submitted,

22 JONES DAY

23 By: /s/ Celeste M. Brecht
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